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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/355,664	10/08/1999	MICHAEL SUNDSTROM	10806-96	6767

7590 05/02/2002

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/02/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/355,664

Applicant(s)

SUNDSTROM ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- ☐ Interview Summary (PTO-413) Paper No(s). ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 4, 6, 9 and 10 have been amended and claims 3 and 22-41 have been cancelled as requested in the amendment of Paper No.12, filed on September 24, 2001. Claims 1, 2, and 4-10 are pending in the instant application.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on September 24, 2001 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. Claims 1-2 and 4-9 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the modified human growth hormone receptor (hGHR) consisting of residues 32-237 of the native molecule of hGHR, capable of being crystallized without being complexed to a ligand molecule, does not reasonably provide enablement for a modified extracellular domain of a cytokine receptor protein, capable of being crystallized without being complexed to a ligand molecule for the reasons of record in section 10 of paper No.10. Briefly, the instant specification fails to provide any guidance on how to identify a "molecular segment which contributes to a disordered structure" of a cytokine receptor protein.

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Without such information one skilled in the art would not be able to modify a cytokine receptor protein in such way that it becomes capable of being crystallized without being complexed to a ligand molecule.

Applicant urges that "the original specification teaches that the inventive modifications are easily accomplished by techniques well known in the art" (see page 5, first paragraph of the Response). However, a patent is granted for a complete invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that: "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". Therefore, the instant specification is not enabling because one can not following the guidance presented therein and practice the claimed method without first making a substantial inventive contribution.

Applicant further refers to enablement requirements with reference to *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). Applicant's attention is directed to MPEP 2164.04, "A specification disclosure which contains a teaching of the manner and process

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of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis” (emphasis added). The Examiner strongly disagrees with Applicant’s statement that “The present specification disclosure contains a teaching of the manner and process of making the modified cytokine receptor protein in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented” (page 6, first paragraph of the Response). On the contrary, the instant specification fails to present teachings that are commensurate with the scope of the claimed invention because it does not identify those specific structures, which define a “molecular segment which contributes to a disordered structure”, therefore the claims 1-2 and 4-9 are rejected under 112, first paragraph, scope of enablement. One skilled in the art would not expect that without knowledge of what is defined by a “molecule segment which contributes to a disordered structure” any cytokine receptor protein can be modified in order to become capable of being crystallized without being complexed to a ligand molecule without undue experimentation. A skilled practitioner would not be able to extrapolate a single working example of a modified hGHR consisting of residues 32-237 of the native hGHR molecule to practice the full scope of the claimed invention with any cytokine receptor proteins.

Thus, taking into consideration the nature of the invention, the unpredictable art of protein crystallization, the lack of guidance and working examples provided in the specification,

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it becomes clear that it would require undue experimentation for the skilled artisan to discover how to make and use the full scope of Applicant's invention, as currently claimed.

6. Claims 1-10 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is indefinite because it is not clear what are the metes and bounds of "a molecule segment which contributes to a disordered structure". Applicant argues that the term "a molecule segment which contributes to a disordered structure" is definite and supported by the specification. The Examiner's opinion on the subject was fully explained earlier. Briefly, if this term was defined by the instant specification, then a skilled artisan would be able to practice the full scope of the claimed invention without undue experimentation.

8. Claims 4 and 5 are indefinite because the extent of truncation is not defined. Applicant asserts that term "truncation" is well known and definite to one of ordinary skill in the art (page 7, second paragraph). The Examiner agrees that the term itself is defined, however, it is a relative term and unless a point of reference (like corresponding amino acid structure) is given, the claims are directed to indefinite structure.

9. Applicant argues further that claims 7 and 8 are definite because "the order of removal [of amino acid residues] in achieving the desired extent of truncation is not critical" (page 8, second paragraph). The examiner, again, disagrees because the precise information about truncating the molecule of hGHR is critical for clearness of the claim. Unless such information is provided, the precise molecular embodiment of the claimed modified protein cannot be defined.

10. Claims 2, 6, 9 and 10 are indefinite for being dependent form the indefinite claims.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyer can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *oc*
May 1, 2002



JOHN ULM
PRIMARY EXAMINER
GROUP 1800